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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/732,954	12/11/2003	Alexander Sulakvelidze	62610.000043	9240
21967 7590 05/31/2007 HUNTON & WILLIAMS LLP INTELLECTUAL PROPERTY DEPARTMENT 1900 K STREET, N.W. SUITE 1200 WASHINGTON, DC 20006-1109			EXAMINER KINSEY, NICOLE	
			ART UNIT 1648	PAPER NUMBER
			MAIL DATE 05/31/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/732,954	Applicant(s) SULAKVELIDZE ET AL.	
	Examiner Nicole E. Kinsey, Ph.D.	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 103-124 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 103-124 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The rejection of claims 88-90, 91, 93, 97 and 99-102 under 35 U.S.C. § 102(b) as being anticipated by Jones et al. (EP 0 414 304 A2) is moot in view of applicants' cancellation of the claims.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 110-115 are rejected under 35 U.S.C. 102(b) as being anticipated by Jones et al. (EP 0 414 304 A2).

The claims are drawn to a method of sanitizing a hard surface located in an area accessed by immunocompromised patients comprising: (a) providing a hard surface located in an area accessed by immunocompromised patients; (b) providing a composition comprising at least one bacteriophage; (c) applying the composition to the hard surface; and (d) reducing the microbial count on the hard surface by at least about one log.

Jones et al., discloses a method for sanitizing a hard surface comprising providing a hard surface, providing a composition comprising at least one

bacteriophage, applying the composition to the surface and significantly reducing the microbial count (see abstract and col. 6, lines 17-28).

Jones et al. further discloses that the bacteriophage can be used to clean a hard surface such as a toilet bowl. It is common knowledge that toilet bowls and other hard surfaces are located in hospitals where patients, including immunocompromised patients (AIDS patients, organ transplant patients, patients undergoing chemotherapy), receive treatment. It is also common knowledge that hospitals notoriously have problems with nosocomial infections due to poor infection-control policies.

Furthermore, as the method steps of Jones et al. are the same as recited in applicants' claims, the method of Jones et al. would inherently reduce the microbial count on the hard surface by at least about 1 log.

Claim Rejections - 35 USC § 103

The rejection of claims 92, 94-96 and 98 under 35 U.S.C. § 103(a) as being unpatentable over Jones et al. (EP 0 414 304 A2) in view of Day et al. (GB 2 253 859) and Youderian et al. (WO 98/47521) is moot in view of applicants' cancellation of the claims.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 103-109 and 116-124 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jones et al. in view of Holzman (Genetic Engineering News, 1998, 18(18):1), and Day et al.

The claims are drawn to a method of sanitizing a hard surface comprising: (a) providing a hard surface; (b) providing a composition comprising at least one bacteriophage that targets a resistant bacterium; (c) applying the composition to the hard surface; and (d) reducing the bacterial count on the hard surface by at least about one log.

The teachings of Jones et al. are outlined above.

Jones et al. does not teach using phages that target resistant bacteria nor sanitizing equipment. However, Day et al. discloses the use of bacteriophage compositions to treat or prevent infestation of microbes. The phage composition can be applied to hard surfaces such as floors and drains (page 1, last full paragraph). (It is

common knowledge that floors and drains are found in hospitals, farms, homes, etc.) Holzman teaches the use of phages to treat multi-drug resistant bacteria and vancomycin-resistant enterococci (VRE) (see pages 1 and 12). Holzman also discloses that hospitals are experiencing outbreaks of VRE (Other scientists pointed out the need for hospitals to examine their infection-control practices. According to William Martone, M.D., senior executive director, National Foundation for Infectious Diseases, once the first outbreaks of vancomycin-resistant enterococci (VRE) were reported in the mid-1980s, experts realized that the pathogen would eventually spread throughout hospitals. Indeed, since that time, reports of VRE have increased 20-fold.) (see page 12). Further, Holzman states that "VRE accounts for about 25% of nosocomial blood stream infections by enterococcus, approximately 30 cases a month here at the University of Maryland Medical System." Holzman also discloses plans to target pathogens that plague livestock, such as *Salmonella* in meat, poultry and eggs, and *E. coli* 0157, as a way of potentially clearing the poultry yards of *S. enteriditis*. Holzman states that "[u]p to 75% of human cases are acquired from meat, poultry or eggs, and up to 25% of broiler chickens and 18% of turkey carry that organism." (see page 48).

It would have been obvious to one of ordinary skill in the art to modify the method taught by Jones et al. and apply phages (e.g., phages that target resistant bacteria) to any hard surface including equipment that could be contaminated or come in contact with bacteria, including resistant bacteria, to sanitize or reduce bacteria on that surface. (One of ordinary skill in the art would also know that hard surfaces, including floors and drains, are found in hospitals, on farms, slaughter areas, processing areas, in buildings,

etc.) One would have been motivated to do so given the suggestions by Holzman that hospitals and farms, including hard surfaces and livestock on the farms, have problems with resistant bacteria. There would have been a reasonable expectation of success given the common knowledge that undesirable microbes exist on farm animals, e.g., such as chickens, cows, pigs, etc.; meat; places where animals and meats are processed; bathrooms; kitchens; hospitals (e.g., equipment in hospitals and other surfaces in hospitals); and public areas and that bacteriophages kill these microbes (see Holzman). It is also common knowledge that bacteria and other microbes are easily transferred to surfaces via contact with an infected source, hence the availability of bleach or other antibacterial/antimicrobial products sold in stores for use in disinfecting kitchens, bathrooms, etc. Thus, the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicole E. Kinsey, Ph.D. whose telephone number is (571) 272-9943. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Nicole E. Kinsey, Ph.D.
Examiner
Art Unit 1648

/nk/

/Stacy B. Chen/ 5-29-2007
Primary Examiner, TC1600